

REMARKS

Claims 30-33 are pending. No new matter has been introduced. Reexamination and reconsideration of the application are respectfully requested.

In the Office Action dated July 1, 2004, the Examiner rejected claims 31-33 based on obviousness-type double patenting as being unpatentable over claim 1 of U.S. Patent No. 6,638,207 ("the '207 patent"). The Examiner also rejected claims 31-33 based on obviousness-type double patenting as being unpatentable over claims 1 and 6 of U.S. Patent No. 6,440,058 ("the '058 patent"). The Examiner indicated that the above rejections would be overcome by a timely filed terminal disclaimer in compliance with 37 CFR 1.130(b).

In response, the Applicant submits herewith a Terminal Disclaimer disclaiming the terminal part of the statutory term of any patent granted on the instant application (i.e., the "'223 application") which would extend beyond the expiration date of the full statutory term of the '207 patent or the '058 patent. The fee for filing a Terminal Disclaimer is enclosed.

In the Office Action dated July 1, 2004, the Examiner rejected claim 30 under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 3,351,049 to Lawrence (hereinafter referred to as "Lawrence" or the "Lawrence reference"). Claim 30 was also rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 4,784,116 to Russell, Jr. et al. (hereinafter referred to as "Russell" or the "Russell reference"). These rejections are respectfully traversed.

Pending claim 30 recites as follows (emphases added):

30. A radioactive seed for use in radiation therapy, the radioactive seed comprising:  
a sealed housing having an internal cavity;  
a plurality of separate carrier units disposed within, and distributed at one end of, the  
cavity, each said carrier unit being impregnated with a radioisotope as a  
radiation source; and  
a plurality of X-ray detectable markers disposed within, and distributed at an  
opposing end of, the cavity, wherein the distribution of the plurality of X-ray  
markers reveals an orientation of the radioactive seed when the seed is  
exposed to an X-ray photography.

Thus, claim 30, as currently pending, expressly requires that a plurality of carrier units be  
distributed at one end of the internal cavity, and that a plurality of X-ray detectable markers be  
distributed at the opposite end of the internal cavity.

In rejecting claim 30 over Lawrence, the Examiner asserts that:

Lawrence teaches a sealed container (28), a plurality of separate carrier units (27a and 27b), and an X-ray marker (26). The embodiment of Figure 4 includes a housing, a carrier and an X-ray marker (31). The marker (31) is linear and therefore reveals the linear orientation of the radioactive seed. It is well known that to define a line one needs two points. It would have been obvious to one of ordinary skill in the art at the time the invention was made to include at least two spheres (26) in the embodiment of Figure 3 as a duplication of components such that to gain the advantage of being able to determine the linear orientation of the seed as can be done with the embodiment of Figure 4. Duplicating the components of a prior art device is a design consideration with the skill of the art . . . To arrange the plurality of carrier units and X-ray markers in any pattern, such as the carrier units at one end of the cavity and the X-ray markers at the other end, would have been obvious to one

skilled in the art since it is well known that different patterns are used depending on the desired treatment pattern in the body and the specific area of the body to be treated. Therefore to select any particular arrangement of the carriers and markers to produce a specific distribution pattern based on the intended use of the device would have been obvious. *See* Office Action, p. 3.

First, it is respectfully submitted that it would not have been obvious to “include at least two spheres (26) in the embodiment of Figure 3 as a duplication of components such that to gain the advantage of being able to determine the linear orientation of the seed as can be done with the embodiment of Figure 4”. To begin with, Lawrence itself could have suggested introducing such a variation into the embodiment of Figure 3; but it does not do so. Rather, it introduces the embodiment of Figure 4 in order to obtain a better determination of the position of the radioactive seed (10). As Lawrence explains:

The geometrical disposition of these high atomic numbered materials within the container is especially important in view of their inherent absorption of the low energy X-rays which are provided by the radioisotope in the seed. If large amounts of such high atomic number and dense material were located about the seed, it would severely attenuate radiation therefrom and materially increase the amount of the total radioisotope required for a given strength, making for very inefficient utilization of the radioactivity. Col. 7, lines 16-26. (Emphasis added).

In other words, contrary to the Examiner’s assertion, Lawrence not only does not disclose or even suggest multiplication of the number of X-ray marker balls (26), it teaches against such multiplication because of the effect that a plurality of such balls would have on the intended radiation from the seed. It is in attempting to avoid such an effect that Lawrence introduces the embodiment of Figure 4 (where the intended radiation is pointed away from the axial wire (31)) as opposed to an embodiment where the number of X-ray marker balls (26) is merely multiplied.

Moreover, there is no disclosure, teaching, or suggestion in Lawrence to support the Examiner's assertion that "to arrange the plurality of carrier units and X-ray markers in any pattern, such as the carrier units at one end of the cavity and the X-ray markers at the other end, would have been obvious to one skilled in the art". In fact, Lawrence teaches away from any such arrangement, where a plurality of carrier units may be localized at one end.

More specifically, Lawrence provides that an object of the invention is to provide a radiation source "in which the radioactive material is uniformly distributed throughout the seed interior so as to prevent localization of the radioactive material and consequent undesirable point source effects." Col. 2, lines 29-34. (Emphasis added). In addition, the "radioisotope is preferably uniformly distributed along the carrier body 12 to avoid having a point source and to maintain a permanent distribution of the radioactive isotope in a fixed bed throughout the extent of the seed." Col. 4, lines 3-6. (Emphasis added). *See also* col. 5, lines 17-20 *and* col. 6, lines 5-7. Thus, with specific regard to the embodiments of Figures 3 and 4, Lawrence concludes that "the location of the high atomic number material should be such as to permit as uniform a radiation pattern as possible from the seed."

In short, it is respectfully submitted that neither the number, nor the placement, of the carrier units and the X-ray markers as claimed herein would have been obvious over Lawrence as the latter teaches away from not only the multiplication of the X-ray marker balls, but also the localization of either the X-ray markers or the carrier units. It is therefore respectfully requested that the rejection of claim 30 over Lawrence be withdrawn.

With respect to the Russell reference, the Examiner asserts that:

Russell, Jr. et al teaches a sealed container (12), a plurality of separate carrier units (14) and an X-ray marker (18). A modification of Russell, Jr. et al to include a plurality of markers and the specific distribution of the carrier units and markers within the housing would have been obvious for the same reasons as discussed with respect to Lawrence. *See* Office Action, p. 4.

However, Russell does not disclose, teach, or suggest a plurality of X-ray markers, let alone distribution of such a plurality of markers at one end. In fact, in describing the invention thereof, Russell provides that:

A rod-shaped marker 18 is interposed between the two pellets 14. The marker 18 is formed of X-ray opaque material to provide a means of visualizing seed 10 after the seed has been implanted within the body of a recipient. Although the marker is highly shielding of the low-energy X-rays emitted by the palladium-103 in the pellets 14, the disposition of the opaque marker 18 between two X-ray-emitting pellets serves to assure that a substantially isotropic angular distribution of X-rays is emitted from the seeds. Col. 4, lines 55-64. (Emphasis added).

Thus, again, contrary to the Examiner's assertion, there is no teaching, or even suggestion, in Russell that multiple X-ray markers be used, and certainly no disclosure, teaching, or suggestion that any such markers be distributed at one end of the capsule 12 while the pellets 14 are distributed at a second, opposite end. In fact, in teaching away from any such arrangement, Russell emphasizes the importance of positioning the marker 18 between the two pellets 14.

It is also noted that, in alternative embodiments, Russell goes even further in teaching away from the separation and localization of the markers, on the one hand, and the pellets, on the other. Thus, for example, with reference to Figure 2, Russell provides that "the activated palladium-102 designated by numeral 52 is coated on a spherical palladium base 54 which acts as an X-ray marker."

Col. 4, lines 65-67. In other words, the marker is not even separate from the pellet, much less at an opposite end of the capsule.

Therefore, based on the above, it is respectfully submitted that, in sharp contrast to the requirements of claim 30, Russell does not disclose, teach, or even suggest the multiplication of X-ray markers or the separate distribution of the markers and the pellets at opposite ends of the cavity. Rather, it only teaches away from these features. As such, it is respectfully submitted that claim 30 is not obvious over Russell, and it is respectfully requested that the rejection of claim 30 on this basis be withdrawn.

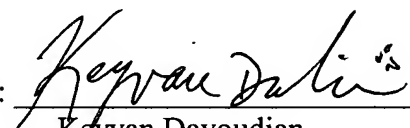
The Applicant believes that claims 30-33 are in condition for allowance, and a favorable action is respectfully requested. If, for any reason, the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance.

Respectfully submitted,

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